

REMARKS

Entry of the foregoing, and further and favorable consideration of the claims, in light of the foregoing amendments and the following remarks, are respectfully requested.

By the present Amendment, Claims 30 and 39 have been amended to delete the "from" which the Examiner maintained was redundant in the phrase "of from". As such, withdrawal of this objection is respectfully requested.

Claim 30 has also been amended to recite that the differential diagnosis distinguishes the North American strain from the European strain of porcine reproductive and respiratory syndrome virus (PRRSV). Claim 30 has also been amended to clarify that "said first and second primers selectively hybridize to said North American strain and at least one of said first and second primers does not hybridize to a European PRRSV strain, wherein said European strain is Lelystad, resulting in amplification of said North American strain but no amplification of said European strain."

Applicants submit that distinguishing the North American strain from the European strain of PRRSV is inherent in the term "differential diagnosis", as is the hybridization to and amplification of the North American strain but not the European strain.

In addition, Claims 30 and 39 have been amended to specify that the primer must bind to the North American or Iowa strain ISU-12 (VR 2385). Claims 30 and 39 already specified that the European strain is Lelystad virus.

The Examiner has rejected Claims 30, 31, and 39-41 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. This rejection, to the extent it applies to the claims as amended, is respectfully traversed.

With respect to Claims 30 and 31, the claims are directed to differentially diagnosing, i.e., distinguishing, North American PRRSV from European PRRSV. The claim is not intended, as the Examiner purports, to identify a particular strain of PRRSV. As shown in Figure 17 of the present application, the nucleotide sequences of the North American strains, in particular the Iowa strains of PRRSV (e.g., ISU-1894, ISU-22, ISU-79, ISU-55, ISU-3927), have a very high degree (i.e., >90%) of sequence identity across their genomes (see, e.g., U.S. Patent No. 6,773,908 which includes additional sequence comparisons of the Iowa strains) as compared to the European strains, e.g., the Lelystad virus (i.e., only about 60% identity across the genome). As such, the primer sets claimed in Claims 30 and 31 are designed to bind to any or all of the Iowa North American strains (ISU-12 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475)) and not to the European strain, and therefore distinguish (hence, "differential diagnosis") the North American strain from the European strain. By being able to differentially diagnose whether a pig is infected with a North American strain versus a European strain, one can tailor treatment and/or prevention to the molecular characteristics of the virus. For the purpose of expediting prosecution, Claim 30 has, however, been amended to specify that the primer must bind to at least ISU-12 (VR 2385).

In contrast, Claims 39-41 are directed to primer sets which bind to the North American/Iowa strains of PRRSV as well as the European/Lelystad strain. These

primers are not intended to distinguish any PRRSV strain from any other. Rather, these primer sets are intended to identify whether a pig is infected with any PRRSV, be it North American or European, because the sequences are chosen from stretches of nucleotide sequence which are highly conserved among all strains of PRRSV. For the purpose of expediting prosecution, Claim 39 has, however, been amended to specify that the primer must bind to at least ISU-12 (VR 2385) as well as Lelystad.

In light of the foregoing, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected Claims 30, 31, 39 and 40 under 35 U.S.C. §112, first paragraph as allegedly not being adequately described by the specification. This rejection, to the extent it applies to the claims, as amended, is respectfully traversed.

With respect to Claims 30 and 31, the Examiner alleges that “[t]here is no indication in the claim that the first or second primer does not or cannot bind to a portion of an Iowa strain that is conserved in the Lelystad strain.” By the present Amendment, Applicants have amended Claim 30 to recite that “said first and second primers selectively hybridize to said North American strain and at least one of said first and second primers does not hybridize to a European PRRSV strain, wherein said European strain is Lelystad, resulting in amplification of said North American strain but no amplification of said European strain.” While Applicants submit that this recitation was inherent in the claim prior to amendment, this explicit recitation makes it clear that the primers of Claims 30 and 31 are indeed “limited to amplifying sections of an Iowa PRRSV genome that may be different from Lelystad.”

Moreover, the specification clearly states at p. 41, ll. 19-25 that “[a] region where a deletion occurs in one of the sequences (e.g., of at least 5 nucleotides) can be used as the basis for preparing a selective primer for selective amplification of the polynucleic acid of one strain or type of PRRSV over another (e.g., for the differential diagnosis of North American and European PRRSV strains).” Such regions can be clearly identified from the sequence comparisons present in at least Figures 8, 10, 11, 17, 18, 21 and 22. As such, withdrawal of the rejection to the extent it applies to amended Claim 30 and to Claim 31 is respectfully requested.

With respect to Claims 39-41, the Examiner alleges that because the recited primers only cover a limited portion of the genome, then they are insufficient. Applicants maintain that the region covered by the primers is totally irrelevant. Indeed, where an animal is infected with a PRRSV virus, the entire genome of that virus will be present in infected tissues. As such, primers that bind to only a limited portion of that genome should still amplify that portion, and as such, provide a positive result.

In light of the foregoing, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected Claims 30, 31, and 39-41 under 35 U.S.C. §112, first paragraph as allegedly not being enabled by the specification. This rejection, to the extent it applies to the claims, as amended, is respectfully traversed.

The Examiner alleges that the primers encompassed by the claimed kits identify any PRRSV, not merely the Lelystad and VR 2385 strains. As noted above, Claim 30 has been amended to make it clear that the primers must bind to PRRSV strain ISU-12 (VR 2385), and that at least one of the primers does not bind to the Lelystad virus. Likewise, Claim 39 has been amended to make it clear that the

primers must bind to PRRSV strain ISU-12 (VR 2385) as well as Lelystad virus. In light of the foregoing amendments and remarks, withdrawal of this rejection is respectfully requested.

As such, Applicants submit that the claims are fully described and enabled by the specification. Further and favorable action in the form of a Notice of Allowance is believed to be in order, and is earnestly solicited.

If the Examiner has any questions regarding this amendment, or the application in general, she is encouraged to contact the undersigned directly so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: March 28, 2005

By: Sharon Crane
Sharon E. Crane, Ph.D.
Registration No. 36,113

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620